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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/688,015      | 10/13/2000  | Junying Yuan         | 00742/056003        | 7472             |

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EXAMINER

SMALL, ANDREA D SOUZA

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 11/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/688,015

Applicant(s)

YUAN ET AL.

Examiner

Andrea D Small

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-41 is/are pending in the application.
- 4a) Of the above claim(s) 3-8, 11-16, 26-31 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 10, 17-25, 32-37 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *I. Applicant's Response:*

Applicant's response, supplemental IDS and declaration dated 9/9/2002 have been received and entered as papers no.14, 15 and 16 respectively.

### *II. Amendments and Arguments:*

(a) Claims 1-2 have been cancelled. Therefore pending claims are 3-41 of which claims 3-8, 11-16, 26-31 and 38-40 are withdrawn from consideration as being drawn to non-elected claims 37 CFR 1.142(b).

(b) Rejection under 35 USC 112, first paragraph:

To provide enabling disclosure for making the derivatives of the compounds employed in the method claims that are currently under examination, the Applicants have provided a declaration under 37 CFR 1.132. Applicants assert, "A patent need not teach, and preferably omits, what is well known in the art." Therefore, the Applicants claim that the declaration should be sufficient to indicate that the 'how to make' requirement under the statute will be satisfied since the process for preparing the derivatives is well known in the art. The examiner respectfully disagrees.

First, *In re Buchner*, 929 F. 2d 660, 18 USPQ 1331 (Fed. Cir. 1991) held that "Affidavits or declarations purporting to explain the disclosure of an application sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite." '[H]ow to make' the derivatives employed in the instant method claims are essential to the use of said compounds and making said derivatives are not well known in the art. Making derivatives of a compound is unpredictable; such preparations depend on the structure of the compound,

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positions that need to be protected from substitution, positions that need to be opened for substitution, etc. Thus, this affidavit cannot substitute or establish facts that the specification should itself recite.

Second, the declaration itself is deficient in that it does not provide what the level of skill in the art was at the time of the filing of the instant application, it fails to establish whether the source materials, reagents, etc were available at the time of the filing of the instant application, and the references in the declaration are non-US patents, which cannot be incorporated into the specification as they relate to essential matter in the application. All of these deficiencies lend to the fact that it is unclear when Applicants had possession of their invention and if it was enabled at the time of the filing of the instant application. Enablement of these derivatives should have been recited in the specification at the time of the filing of the instant application and the declaration provided is not acceptable to establish these essential facts. See MPEP 716.09.

Hence, the rejections as to claims 9-10, 17-25, 32-37 and 41 are maintained.

(c) Rejection under 35 USC 112, second paragraph:

Amendments to claims have overcome said rejections.

### ***III. Maintained Rejections:***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10, 17-25, 32-37 and 41 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

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one skilled in the art to which it pertains, or with which it is most nearly connected to make the invention. Instantly, Applicant claims methods of using derivatives of compound, namely compound ID # 115807. The specification does not provide an adequate description of the manner in which the derivatives are made. The step, reagents, temperatures, pH, etc involved in making derivations of the compounds is not provided. The limited disclosure does not provide one of ordinary skill in the art full, clear, concise and exact terms by which the claimed subject matter is made. By including a list of references, the rejections may be overcome. However, Applicants should note that the introduction of new subject matter into the specification would raise the issue of new matter.

***IV. Maintenance of Finality:***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***V. Salutation:***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small, whose telephone number is (703) 305-0811. The examiner can normally be reached on Monday-Thursday from 8:30 AM - 7:00 PM.

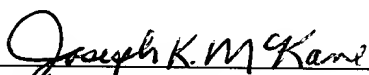
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1234

Andrea D. Small  
October 29, 2002

  
\_\_\_\_\_  
Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626  
Technology Center 1